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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,825	12/15/2006	Paul Boulange	0040-0165PUS1	2356

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EXAMINER
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DESAI, ANAND U

ART UNIT	PAPER NUMBER
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1656

NOTIFICATION DATE	DELIVERY MODE
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01/06/2011

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/589,825	<b>Applicant(s)</b> BOULANGE ET AL.	
	<b>Examiner</b> ANAND U. DESAI	<b>Art Unit</b> 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 3/17/2010 & 10/19/2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-14, 30 and 31 is/are pending in the application.
- 4a) Of the above claim(s) 1-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 30 and 31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>20100317; 20101019</u>  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### **Continued Examination Under 37 CFR 1.114**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on March 17, 2010 and October 19, 2010 have been entered.

2. Claims 15-18 and 24-29 have been cancelled.

3. Claims 1-14 have been withdrawn previously.

4. Claims 30 and 31 are currently under examination.

5. The indicated allowability of claim 30 is withdrawn in view of the newly discovered reference(s) to Lengsfeld et al. (US 2003/0232969 A1; 3/17/2010 IDS Document AA\* ).

Rejections based on the newly cited reference(s) follow.

### **Withdrawal of Rejection(s)**

6. The rejection of claims 24-26 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn based on the amendment to cancel the claims.

7. The rejection of claims 15-18 and 24-29 under 35 U.S.C. 103(a) as being unpatentable over WO 92/04367 in view of EP 0 570 916, and Winge (U.S. Patent 6,399,357 B1) is withdrawn based on the amendment to cancel the claims.

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### **Information Disclosure Statement**

8. The information disclosure statements (IDSs) submitted on March 17, 2010 and October 19, 2010 are being considered by the examiner. The 1449 forms are attached with the instant office action.

### **Claim Rejections - 35 USC § 112**

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 30 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. The ionic strength is not identified by units of either Molarity or Molality? What are the units of ionic strength?

### **Claim Rejections - 35 USC § 103**

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Regarding the method of forming the aqueous albumin solution, it is the position of the examiner that such limitations in the product claim are merely product-by-process limitations. The claims recite that the aqueous albumin solution are formed via a nanofiltration method; however these claims are drawn to a product. Regardless of how the product is made the components remain the same and as such the process of making the product bears little patentable weight, unless the process produces a materially different product. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious

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from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

15. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ohmura et al. (EP 0 570 916; previously cited) in view of Lengsfeld et al. (US 2003/0232969 A1) and Winge (U.S. Patent 6,399,357 B1; previously cited).

Ohmura et al. discloses a process for producing recombinant human serum albumin and a pharmaceutical preparation containing the same. Although, the primary reference suggests the use of an alternative method for purification of albumin, and in view of this, one of ordinary skill in the art would have understood that additional steps to obtain an albumin of sufficient purity; therefore, one of ordinary skill in the art would be motivated to look for a supplementary steps which could assure the intended product to achieve the required purity. The claim is also drawn to a process that comprises steps.

Filtration is routine operation to improve the purity of a protein and moreover ultrafiltration and removal of salts are used in EP 0 570 916. Further, one ordinary skill in the art would be motivated to employ nanofiltration, because Winge discloses the purification albumin using a nanofilter (see particularly claims 14-17 and 35-42). Furthermore, Lengsfeld et al. disclose the removal of virus from protein solutions using a nanofiltration step (see claim 6).

Further, the production of albumin from genetically modified yeast is a routine technique (See e.g., EP 0 570 916). The reference of EP 0 570 916 teaches a method of purifying human serum albumin by combination of steps subjected to ultrafiltration, heat treatment, acid treatment and another ultrafiltration, followed by subsequent treatments with a cation exchanger, a hydrophobic chromatography carrier and an anion exchanger, and by salting-out to thereby

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obtain a pure form of human serum albumin free of contaminants (See abstract). The reference also discloses a method where use is made of NaCl solution in acetate buffer, and in general demonstrates that fatty acids and acids and their salts to be useful for elution from albumin from cation exchange resins, and a method for albumin purification, where a cation exchanger step precedes an anion exchange step (See e.g. summary of the invention).

Thus, the advantages of using alternative chromatographic techniques for albumin purification is clearly disclosed. Moreover, such features of purifications are known or suggested in the art, as seen in the secondary references, and including such features into albumin purification methods of the primary reference, would have been obvious to one of ordinary skill in the art to obtain the known and recognized functions and advantages thereof for the intended purpose of producing pure albumin.

Therefore, in view of the above, and in view of the combined teachings of the prior art; one of ordinary skill in the art would have been motivated at the time the invention was made to use the already known method of purifying albumin by nanofiltration to eliminate impurities from purified albumin, absent of sufficient objective factual evidence or unexpected results to the contrary.

### **Conclusion**

16. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANAND U. DESAI whose telephone number is (571)272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571)272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

January 3, 2011

/ANAND U DESAI/

Primary Examiner, Art Unit 1656